DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

OCT - 7 1999 8923

The Honorable Barbara Boxer
United States Senator
1700 Montgomery Street, Suite 240
San Francisco, California 94111

Dear Senator Boxer:

Thank you for your letter of August 3, 1999, on behalf of your constituent, Mr. Christopher E. Grell of San Francisco, California, concerning the use of synthetic sources of ephedrine in dietary supplements containing ephedrine alkaloids.

We appreciate the information that Mr. Grell provided in his letter to you. The information will be useful to the Food and Drug Administration (FDA or the Agency) in evaluating the use of synthetic ephedrine hydrochloride in dietary supplements and its potential association with adverse effects in consumers using such products. As you may be aware, on June 4, 1997, FDA published a proposed rule in the *Federal Register* regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. The ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products that contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries.

As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products that contained, or were suspected of containing, ephedrine alkaloids. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors and headaches, to seizures, heart attacks, strokes and death. Since January 1997, FDA has continued to receive additional reports of adverse events associated with the use of these products. At this juncture, the Agency is in the process of reviewing data on Adverse Event Report's received after the publication of the proposed rule and additional scientific evidence collected by the Agency.

95N-0304

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After completing this latest round of investigation and analytical review, FDA will determine its degree of support for the requirements on the proposed rule or for alternative regulatory actions. In this regard, we are forwarding a copy of Mr. Grell's letter to the docket for the rulemaking on dietary supplements containing ephedrine alkaloids, Docket #95N-0304.

We trust this information responds to your concerns. If we may be of further assistance, please contact us again.

Sincerely,

Timothy S Tynan

for Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(#95N-0304)

BARBARA BOXER
CALIFORNIA

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August 3, 1999

Ms. Diane Thompson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
HFW-1, Room 15-55
Rockville, MD 20857

Dear Ms. Thompson:

I am writing on behalf of Senator Boxer's constituent, Christopher Grell, regarding the use of controlled substances in the making of dietary supplements. Enclosed please find a copy of Mr. Grell's correspondence.

Senator Barbara Boxer requests your review and consideration of this matter. Any assistance or information you can provide in response to the concerns expressed by Mr. Grell will be most appreciated. Please reply to Senator Boxer at her San Francisco office, Attention: Leah Simon-Weisberg.

Thank you for your attention to this matter.

Sincerely,

Eric J. Vizcaino
Director of Constituent Services

EJV/lsw
Enclosure
cc: Mr. Christopher Grell

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URGE

FDA

May 10, 1999

Honorable Senator Diane Feinstein
United States Senate
Washington, D.C. 20510-0505

Honorable Senator Barbara Boxer
United States Senate
Washington, D.C. 20510-0505

Re: Dietary Supplements and Drugs that rae Used

Dear Senators Boxer and Feinstein:

Please listen. I recently obtained sworn testimony that proves that at least one Dietary Supplement Maker is manufacturing a product sold as dietary supplements which is being spiked with the drug ephedrine, a controlled substance. I can also prove that this company received over 3,500 consumer complaints involving adverse reactions, and never reported a ingle one to any government agency. (See enclosed)

I wrote to Senator Hatch to alert his office to this fact (the company is based in Utah). I never received a response. I also contacted the FDA, the DEA and the California Food and Drug Branch. Presently, I am waiting to see what, if any, action they might take. (It has been well over a month.)

These products are adulterated, unsafe drugs being sold not just in California, but around the country. Consequently, I hope that your office will look into why this is allowed to occur and what, if any, federal and/or State action is planned. I also hope that you will contact Senator Hatch in case he did not receive my letters. This way, it is on record that he has been informed of this problem which, hopefully, will preclude him from standing up in front of the American public like he did when *Prime Time Live* aired a story in 1994, which I was on, and proclaim that this industry makes safe products, has few consumer complaints and does a "good job of policing itself." (See enclosed)

If you need supporting documents in addition to what is enclosed, please have your office contact me.

Thank you.

Very truly yours,

Christopher E. Grell

CEG:lm
enclosure